

**114th Meeting of the
National Cancer Advisory Board**

**June 12, 2000
7:00 p.m. - 9:00 p.m.
Bethesda Hyatt Regency Hotel
Bethesda, Maryland**

**MEETING SUMMARY
SUBCOMMITTEE ON CANCER CENTERS**

ATTENDEES

NCAB MEMBERS

Dr. French
Dr. Nienhuis
Dr. Armitage
Dr. Freedman
Dr. Ramirez
Dr. Sharp

NCI STAFF

Dr. Wittes
Dr. Kimes
Dr. Kalt
Dr. Bryant
Dr. McCormick
Dr. Bhorjee
Dr. Hammond
Dr. Holmes

PUBLIC

Dr. Vaitkevicius
Dr. Herberman

HIGHLIGHTS

The National Cancer Advisory Board, Subcommittee on Cancer Centers, met to review proposed changes to the Cancer Center Support Grant (CCSG) Guidelines. A list of 15 recommended changes were reviewed and discussed. The subcommittee voted to accept all 15 changes.

MEETING SUMMARY

Dr. Kimes welcomed participants of the Subcommittee on Cancer Centers, National Cancer Advisory Board. The meeting convened at 7:00 p.m. on June 12, 2000, at the Bethesda Hyatt Regency Hotel in Bethesda, Maryland.

Dr. Nienhuis introduced the agenda, which contained one item—to discuss changes to the Cancer Center Support Grant Guidelines (CCSG). Dr. Kimes stated that the process of recommending changes to the guidelines is an ongoing process that involves oversight by the National Cancer Advisory Board (NCAB). The proposed changes are listed below, referenced according to the applicable designation in the current CCSG Guidelines. Relevant discussions are recorded, as well as results of the decision of the subcommittee.

Change #1: Part I, 10.3 Shared Resources and Services

There are many low throughput, high technology shared resources underutilized in cancer centers; this change articulates the need for these kind of resources and the standards for their evaluation. A second change is meant to clarify the role of and strengthen clinical protocol and data management shared resources.

Motion : The subcommittee passed this motion unanimously.

Change #2: Part I, 10.3.3 Informatics

Many centers are hesitant to request funds for informatics support even though the need for informatics support is becoming essential to biomedical research. The proposed change will encourage centers to apply for informatics support and provides the criteria for evaluating informatics resources.

Motion : The subcommittee passed this motion unanimously.

Change #3: Part I, 10.5 Interactions with Private Industry

Dr. Kimes commented that this has been an area of great confusion in the past because cancer centers haven't had a clear idea of the ground rules for interacting with industry. A new section is included at the very beginning of the CCSG Guidelines that encourages centers to interact with industry. The guidelines for interacting with industry are very flexible, whether centers are developing industrial drugs or technologies, as long as process is primarily driven by the intellectual contributions of center scientists.

Motion : The subcommittee passed this motion unanimously.

Change #4: Part I, 13.1 Ratio Calculations

Dr. Kimes presented background for using the ratio calculation in the application for the CCSG. Reviewers are given this ratio and use it as a reference point to assess the budget levels of center applications. The purpose of this change was to clarify language describing the meaning and significance of the ratio to help both applicants and peer reviewers. Dr. Sharpe asked if it meant that it is more flexible. Dr. Kimes affirmed this concept. The ratio was never meant to be fixed. In addition, ratio information will be given to applicants well before they prepare the application. The subcommittee took part in a long discussion of the practical effects of the ratio in creating a situation where centers would try to manipulate the ratio to increase their budgets, rather than focusing on highlighting the science to be performed under the grants.

Motion : The subcommittee passed this motion unanimously.

Change #5: Part II, 2.5.1 Reviewing Shared Resources
Review of the Application: Site Visit

This change will bring the focus of peer reviewers more on the science and less on the resources. The purpose of this change is to encourage applicants to present resources through poster sessions rather than as individual presentations. This will allow more time for science, but will not eliminate the possibility of presenting a new or complicated resource individually.

Motion : The subcommittee passed this motion unanimously.

Change #6: Part II, 3.2.1 Level of Effort for Senior Leaders and Program Leaders

Currently, the guidelines allow for support of Senior Leaders and the Program Leaders. This change will encourage reviewers to assess the complexity and dimension of each leadership position and avoid the use of formulated approaches for determining percent effort. Presently, about 10 percent of CCSG funding is designated for leadership roles. This change will also encourage centers to ask for what they need in terms of support for leadership roles.

Motion : The subcommittee passed this motion unanimously.

Change #7: Part III, 2.4.1, Part III 2.4.2, Part III, 2.4.3, and Part III, 2.4.4
Developmental Funds

Dr. Kimes explained that a number of areas within the scope of developmental funding need to be addressed. Presently, only 25 percent of a grant budget can be used by a center for developmental funds. The first change is to eliminate the 25% cap. The second change encourages balanced funding across all scientific areas of a cancer center, (e.g. basic, clinical and population sciences). A third change specifically encourages the use of developmental funds for technology development. A fourth change addresses an issue that has been a problem; the centralization of developmental funds totally under the center director with no direct accessibility to the program scientific leaders. There is a need to have the program scientific leaders gain some access to development funds. This is a bottom-up concept and will add tremendous power to the centers ability to concentrate on the mission of the center.

Dr. Sharp commented that the director is the person responsible for managing the developmental funds and this change appears to take away flexibility and the ability to control how the center is operated. Dr. Kalt explained that the purpose of this change is to give directors of the centers adequate flexible funds to manage the grant. Dr. Sharp disagreed that this is workable because it is written in a way that appears that every area of science should receive its proportional share of the Developmental Fund budget. Dr. Nienhuis asked how it should be written. A discussion ensued that resulted in a change to the proposed revision:

the word "equitable" will be removed from this section.

Motion : The subcommittee unanimously approved this revision with removal of the word equitable.

Change #8: Part II, 3.2.5 Center Administration

Dr. Kimes reviewed this change and said that centers need to know how to ask for secretarial and administrative support for Senior Leaders and Program Leaders.

Motion : The subcommittee passed this motion unanimously.

Change #9: Part II, 3.2.6.3 Information Needed in Application on Shared Resources

This change does not add significant new information to the guidelines. It is an attempt to consolidate information required for shared resources in center applications and make it consistent throughout the guidelines. It will put this information in one place, thus helping peer reviewers and applicants. Dr. Sharpe commented that it appears documentation of utilization of the resource is more important than the result of use of the resource. Dr. Kalt said insufficient information forces the reviewers to spend more time on resources and less time on science. This change will make it easier to understand how shared resources are used and what they are intended to do. Dr. Sharpe said it might take a full-time administrative staff to monitor and document the use of shared resources. Discussion of this point was lengthy. Dr. Kimes added that if he asked the centers what they thought about this issue, there would be just as much discussion and controversy generated as with the Subcommittee.

Dr. Kimes promised to review for the Subcommittee how this is working in one year.

Motion : The subcommittee passed this motion with one abstention.

Change #10: Part II, 3.2.8 Protocol-Specific Research Support

The purpose of this change is to ensure that cancer centers have a core group of experienced research nurses and data managers available to conduct innovative research. The current cap of 3 FTEs seems unreasonable for large centers, so the cap is eliminated. This change will emphasize the "core group" concept and will allow centers to include all translational research being conducted in clinical research settings rather than just traditional therapeutic research. This support would not be applicable to population studies.

Motion : The subcommittee passed this motion unanimously.

Change #11: Part III, 4.0 Application Format Future Plans for the Center

This change explicitly provides needed guidance for applicants in describing their plans for future development.

Motion : The subcommittee passed this motion unanimously.

Change #12: Part III Summary 5 Comparison Budget Pages for Review (already in effect)
Change #13: Part III, page 4 Summary 3 Patient Data (to be submitted annually)

These two changes refer to summary information that is required to be reported by centers in their competing and non-competing applications. Summary 5 was removed from the application in a previous revision of the CCSG Guidelines and is being reinstated because peer reviewers insist on having it. In addition, there is a need for annual reporting of new patients and previously treated patients listed by site and participation in local and national trials. This is vital both for the competitive phase of the review and for NCI reporting on the progress of cancer centers.

Dr. Wittes commented that reporting clinical data is a troubling problem. It is beyond dispute that we need this information, but we need to figure out how to do it. Dr. Nienhuis replied that summaries 1, 2, and 4 are required each year; summaries 3 and 5 are only required at the competing stage. This change will keep all the requirements the same except for number 3, which will be required each year.

Dr. Kimes said that if the revisions are accepted by the subcommittee, the NCI will report how this information has been used on two years to the Subcommittee.

Motion : The subcommittee passed this motion unanimously.

Change #14: Summary 4 Protocol Information

These changes to Summary 4 will provide clearer definitions for each of the information items being requested, and will modify and simplify the outlay of the information in the table. There is a need to clarify terms that in the past have been difficult to use in a consistent manner. These revisions will help the centers present data in a consistent manner.

Motion : The subcommittee passed this motion unanimously.

Change #15: Expanded Authority

Dr. Kimes explained that the voting on this revision in only meant to determine the subcommittee's agreement to place cancer centers under Expand Authorities, not on specific wording to be included. This will give the centers the ability to carry over money from year-to-year without using the current cumbersome administrative procedures. It will help both centers and NCI administrators.

Motion : The subcommittee passed this motion unanimously.

Dr. Kimes asked if there were other points of discussion, or new business to be offered for discussion. None was requested.

Dr. Nienhuis adjourned the meeting at 9:20 p.m.

6/14/00
Date

Arthur Nienhuis
Dr. Arthur Nienhuis